

## **REMARKS**

The Applicants thank the Examiner for entering the previously filed amendments and the comments provided in the November 17, 2008 Advisory Action. The Applicants respectfully request reconsideration of the instant application in view of the foregoing amendments and in view of the reasons that follow.

### **I. Status of the Claims**

Claims 1-4 and 11-12 are cancelled and represented as claims 15-20. Claim 15 (previously claim 1) is amended to recite that the composition is to be applied to the subject for a period of time, such that the thickness of the subject's hair after the step (B) is substantially the same or greater than that before the step (B), wherein the period is at least one month. Support of the amendment can be found in, for example, lines 3-16 on page 7 and/or Experiment 4 in the instant Specification as filed. No new matter is introduced, and claims 15-20 are currently pending to be examined on their merits.

### **II. Claim Rejections – 35 U.S.C. § 102**

The Office maintained its rejections to claims 1-4 and 11-12 under 35 U.S.C § 102(b) as allegedly being anticipated by Tajima (US 2002/0192177). The Applicants respectfully traverse the rejections.

Tajima does not anticipate claim 15 or its dependents. In the Final Office Action and the Advisory Action, the Office incorrectly analogizes “hair loss preventing action” and “hair growth promoting action” as disclosed by Tajima with the instantly claimed “maintaining and promoting hair thickening.” *See e.g.*, page 2, Advisory Action. Without acquiescing to the grounds of the rejections, claim 1 (now claim 15) is amended to clarify that the composition is to be applied to the subject for a period of time, such that the thickness of the subject's hair after the step (B) is substantially the same or greater than that before the step (B), wherein the period is at least one month.

Nowhere does Tajima disclose that the thickness of the subject's hair after the application of a composition is maintained or greater than that before the application. In fact, Tajima **does not disclose any comparison of the hair thickness** or diameter as affected by its composition at all. Tajima's method of measuring the growth promotion effect of the composition of Tajima is based on counting the number of hair roots that are in the resting stage (*see* paragraphs [0052] to [0055] Tajima), rather than comparing the thickness of the hair before and after the application of a composition to determine the thickening effect of the composition as instantly claimed.

The Applicants further submit that the Office's assertion that a hair loss preventing action would necessarily maintain the thickness of a hair (page 2, Advisory Action) is incorrect. Tajima defines the ability of hair to grow based on the number of hair roots not in the resting stage, as previously explained, which is not at all analogous to the instantly claimed method, which recites maintaining or increasing the thickness of the hair after the application of a composition. Additionally, prevention of hair loss is not the same as maintaining hair thickness. For example, while no hair loss may occur, the hair can become thinner with time, particularly after one hair growth cycle – this is in contrast to what is instantly claimed. Furthermore, Tajima cannot anticipate the instant claims in view of *Rapoport v. Dement*, 254 F.3d 1053, 1059-60, 59 USPQ2d 1215, 1219-20 (Fed. Cir. 2001). Claim 15 recites “maintaining and promoting hair thickening... a subject **in need thereof**,” and thus it should be construed to refer to the maintaining and promoting hair thickening **only as instantly claimed** and not to encompass the “hair loss prevention” or “hair growth promoting action” of Tajima, which is very different from the instantly claimed effects as already established (*see* Office on page 4 of Advisory Action). *Rapoport*.

Claim 15 recites that the thickness maintaining and promoting effect is observed over a period of time (i.e., at least one month). As shown in Figure 1 of Muller-Rover et al (Exhibit B of the reply filed on October 17, 2008), the anagen growth phase of hair is only about 1-3 weeks. Thus, the instantly claimed method is directed to maintaining or promoting the thickness of hair over **more than merely one phase** of the hair growth cycle. In fact, it refers to at least one complete hair growth cycle. Thus, the Office's rejection based on the analogy of growth (and “thickening”) in only

the anagen phase to the thickening as instantly claimed, citing both Tajima and the Britannica Encyclopedia diagram, should be moot.

Because Tajima does not teach every element of the instant claims, it cannot anticipate the instant claims. Moreover, in view of the foregoing, the Office's rejections directed to the function or mechanism of action for FGF-7, (*see e.g.*, pages 3-4, Advisory Action) should also be moot.

Therefore, the Applicants respectfully request that the rejections be withdrawn.

### **III. Double Patenting**

Claims 1-4, and 11-12 are rejected on the ground of nonstatutory double patenting. The Applicants request that the rejections be held in abeyance until the other rejections are overcome in the instant application. The Applicants request that if double patenting becomes the last remaining rejection in the instant application, the Examiner contact the undersigned representative to consider filing a terminal disclaimer if warranted to overcome such rejection.

### **CONCLUSION**

The Applicants believe that the instant application is now in condition for allowance and respectfully request favorable reconsideration of the application. The Examiner is invited to contact the undersigned by telephone if it would advance the prosecution of the instant application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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